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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,931	07/26/2001	Hilton A. Salhanick	62694-A/JPW/SHS	8253

7590

06/03/2003

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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/915,931

Applicant(s)

SALHANICK ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 17-19, 33-35, 41, 42, 47, 48, 67, 68, 74-76, 88 and 94-135 is/are pending in the application.

4a) Of the above claim(s) 1-8, 12-16, 20-32, 36-40, 43-46, 49-66, 69-73, 77-87, 89-93 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) 9-11, 17-19, 33-35, 41-42, 47-48, 67-68, 74-76, 88 and 94-135 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

DETAILED ACTION

1. Applicant's election with traverse of group I in Paper No. 7 is acknowledged but is moot in light of new restriction necessitated by the cancellation of group I and the addition of new claims 94-129 in Paper No. 7. A new supplemental amendment adds additional new claims 130-135 in new Paper No. 9.
2. Claims 1-8, 12-16, 20-32, 36-40, 43-46, 49-66, 69-73, 77-87 and 89-93, are cancelled.
3. Claims 94-129 in paper No. 7 and claims 130-135 in paper No. 9 were added as new claims.
4. Currently, claims 9-11, 17-19, 33-35, 41-42, 47-48, 67-68, 74-76, 88, and 94-135 are pending and subject to restriction.

New Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 9-11, 41-42, 47-48 and 74-76 drawn to a method of diagnosing a thyroid condition and whether a person treated with thyroxine is receiving proper dosage, determining a concentration of triiodothyronine and TSH, classified in class 436, subclass 536.
 - II. Claims 33-35, drawn to a method of diagnosing a thyroid condition comprising determining the concentration of thyroxine-glucuronide in a sample, classified in class 424, subclass 568.

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- III. Claims 17-19, drawn to a method of diagnosing a thyroid condition, determining a concentration of triiodothyronine-sulfate, classified in class 424, subclass 145.1.
- IV. Claims 67-68 and 88, drawn to a method of determining whether a subject being treated with thyroxine is receiving a proper dosage and a method of monitoring the subject, determining TSH and adjusting dosage of of thyroxine in patient, classified in class 435, subclass 7.1.
- V. Claims 94-101, 110-122 and 132-134 drawn to a method of diagnosing a thyroid condition comprising determining the concentration of TSH and thyroxine comprising binding TSH with an detectable agent classified in class 436, subclass 518.
- VI. Claims 102-109, 123-131 and 135, drawn to a method of diagnosing a thyroid condition and determining if a subject treated with thyroxine is receiving a proper dosage comprising determining the concentration of thyroxine, binding thyroxine with a predetermined amount of detectable thyroxine, classified in class 436, subclass 538.

The inventions are distinct, each from the other because of the following reasons:

- 5. Inventions I-VI are unrelated methods. In the preamble of inventions 1-VI the methods are drawn to processes of diagnosing a thyroid condition and/or determining whether a person treated with thyroxine is receiving the proper dosage. Inventions I-VI are patentably distinct one from the other because they have a different mode of operation in that they detect for different reagents or the same reagents with different

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method steps as in invention IV that includes the step of monitoring the subject and adjusting the proper dosage of thyroxine. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and method steps making them patentably distinct one from the other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Please note that classifications in the restriction are illustrative only and do not represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches, therefore restriction for examination purposes as indicated proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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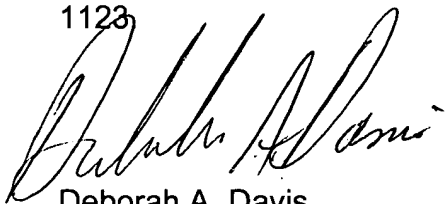
remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123



Deborah A. Davis
CM1, 7D16
May 29, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/02/03